

## Remarks

### Amendments to the Claims

The amendments to the claims do not add new matter. Claim 69 is amended to recite that the HVJ-E “contains no exogenous nucleic acid.” This amendment is supported throughout the specification, *e.g.*, page 17, lines 25-28. See Example 8 of U.S. Patent 7,279,333, which is the English equivalent of JP2001-286282 referenced on page 18, lines 20-24 of the specification. Example 8 of the ‘333 patent plainly distinguishes between an HVJ envelope—as used in the present specification and recited in the pending claims—and an HVJ envelope vector containing exogenous nucleic acid. New independent claim 95, which recites an “empty” HVJ-E, is supported by the same disclosures. New dependent claims 96-98 are supported, for example, on page 23, lines 3-13.

### Rejection Under 35 U.S.C. § 112 ¶ 1

Claims 69 and 92-94 are rejected under 35 U.S.C. § 112 ¶ 1 as not enabled for their full scope. Applicants respectfully traverse the rejection.

The Examiner acknowledges that the specification enables a method of inhibiting tumor cell growth in an animal via intratumoral administration of HVJ-E, but cites a lack of evidence that other routes of administration are effective to support the enablement rejection. As an initial matter, Applicants are not required to provide evidence that HVJ-E inhibits tumor cell growth when administered by other routes. It is the Examiner’s burden to establish a reasonable basis to question why the specification does not enable the claimed methods. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). The Examiner must not only explain why she doubts the statements in the specification’s supporting disclosure, but also must support her assertions “with acceptable evidence or reasoning which is inconsistent with the contested statement.” *In re Marzocchi*,

439 F.2d 220, 224 (C.C.P.A. 1971). Thus, a proper enablement rejection should contain specific findings of fact—supported by evidence—and conclusions based on those findings of fact. See M.P.E.P. § 2164.04.

The rejection does not contain any specific findings of fact or evidence to support the assertion that other routes of administration are not enabled. The Examiner's failure to articulate a reasonable basis for challenging the enablement of the rejected claims alone is fatal to this rejection and is not sufficient to shift the burden to the Applicants. Nevertheless, to advance prosecution, Applicants include with this response a second Declaration under 37 C.F.R. § 1.132 of Toshihiro NAKAJIMA. The Declaration provides evidence that subcutaneous injection of HVJ-E results in a significant level of tumor growth inhibition in a human prostate cancer xenograft model.

There is no scientific or legal basis to support the assertion that claims 69 and 92-94 are not enabled. In fact, the evidence of record demonstrates that the specification does enable the claimed methods. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(b)

Claims 69 and 92 are rejected under 35 U.S.C. § 102(b) as anticipated by EP1170363 (Kaneda). The Examiner cites Kaneda as teaching administration of HVJ-E comprising a luciferase gene. To advance prosecution, independent claims 69 is amended to recite that the HVJ-E contains no exogenous nucleic acid. Kaneda does not teach a method of inhibiting tumor cell growth in an animal by administering a composition consisting essentially of HVJ-E containing no exogenous nucleic acid. Please withdraw the rejection.

Respectfully submitted,

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